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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-16-0733]**

**[Docket No. CDC-2016-0095]**

**Proposed Data Collections Submitted for Public Comment and  
Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS)

**ACTION:** Notice with comment period

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as requires by the Paperwork Reduction Act of 1995. This notice invites comments on Early Hearing Detection and Intervention (EDHI) Hearing and Screening Follow-up Survey.

**DATES:** Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTRY].

**ADDRESS:** You may submit comments, identified by Docket No. CDC-2016-0095 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instruction for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulation.gov, including any personal information provided. For access to the docket to read the background documents or comments received, go to Regulations.gov.

**FOR FURTHER INFORMATION CONTACT:** Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information

they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, and each reinstatement of previously approved information collection before submitting the collect to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and

verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

### **Proposed Project**

Early Hearing Detection and Intervention (EDHI) Hearing and Screening Follow-up Survey (OMB No. 0920-0733, Expiration 08/30/2016)- Reinstatement with Change - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

### **Background and Brief Description**

The Division of Human Development and Disability, located within NCBDDD, promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities. As part of these efforts the Center is actively involved in addressing the early identification of hearing loss among newborns and infants. Congenital hearing loss is a common birth defect that affects 1 to 3 per 1,000 live births, or approximately 12,000 children across the United States annually.<sup>1, 2</sup> Studies have shown that children with a delayed

diagnosis of hearing loss can experience preventable delays in speech, language, and cognitive development.<sup>3 - 5</sup> To ensure children with hearing loss are identified as soon as possible, many states and United States (U.S.) territories have implemented Early Hearing Detection and Intervention (EHDI) programs and enacted laws related to infant hearing screening. The majority of these EHDI programs have adopted the "1-3-6" plan, which consists of three core goals: 1) screening all infants for hearing loss before 1 month of age, 2) ensuring diagnostic audiologic evaluation before 3 months of age for those who do not pass the screening, and 3) enrollment in early intervention services before 6 months of age for those identified with hearing loss.

Federal support for identifying children with hearing loss began with the Children's Health Act of 2000, which authorized federal programs to support EHDI activities at the state level. Since then, funds have been distributed to states via cooperative agreements from the CDC and grants from the Health Resources and Services Administration (HRSA). States are using these federal monies to enhance EHDI programs and develop corresponding tracking and surveillance systems. These systems are intended to help EHDI programs ensure infants and children are receiving recommended hearing screening, follow-up, and intervention services.

The CDC's NCBDDD will fund this work to obtain standardized annual jurisdictional data related to the number of children screened for hearing loss, referred for and receiving follow-up testing (e.g., diagnostic audiologic evaluation). As with the original and reinstated information collection the overall purpose of this updated survey is to consistently gather the aggregate-level data required to assess progress toward the National EHDI Goals.

Proposed changes for the updated survey have been made in response to feedback from respondents and requests for additional information from state and national partners. These updates are intended to further increase the standardization and completeness of the data collected and make the survey easier to complete. These changes include adding new fields to capture data about hearing screening conducted by using one-stage, two-stage, or blended (both one-stage and two-stage) screening protocol. In addition, fields were added to be able to report the number of occurring homebirths and the number of infants not documented to have received recommended screening, diagnostic and/or intervention services, due to reasons such as the infant being adopted, no referral from the Primary Care Physician (PCP)/Ear-Nose-Throat (ENT) specialist and/or due to medical reasons. Several fields have been removed in order to improve data quality and better evaluate whether jurisdictions are meeting the

nationwide benchmarks. The table for reporting type and severity of hearing loss data has been updated so that this data can be reported using only the classification system from the American Speech and Hearing Association (ASHA). The table for reporting demographics has also been updated to include fewer columns, in order to improve data quality and data standardization with the previous sections of the survey.

The collected data will continue to be used in four key ways. First, it will be used to determine annual rates of hearing screening, referral for further diagnostic testing, loss to follow-up, incidence of hearing loss in infants, and enrollment in early intervention. These data will assist in determining if infants and children are receiving recommended EHDI-related services in a timely fashion. The information is intended to be made available through presentations, articles related to EHDI programs and infant hearing loss, and online at: [www.cdc.gov/ncbddd/hearingloss/ehdi-data.html](http://www.cdc.gov/ncbddd/hearingloss/ehdi-data.html).

Second, the data will be used to determine rates of loss to follow-up within different stages of the EHDI process. Aggregated information about maternal race, ethnicity, education, and age will be used to help determine whether rates of loss to follow-up are correlated with any of these demographic variables. As with the most recent reinstatement with change (2013), the updated survey will continue to use same set of demographic data items,

which will make it possible to continue analyzing the association between factors such as maternal race and loss to follow-up, maintain comparability between previous and future data, and minimize burden on respondents by continuing to request the same data that programs are currently collecting and able to report. This information is anticipated to continue to be important in developing methods to help minimize loss to follow-up so all children receive recommended hearing-related services in a timely manner.

Third, the data will be helpful in determining to what extent jurisdictional tracking and surveillance systems are capturing essential information related to follow-up services, identification, and enrollment in early intervention. It will also be used by CDC EHDI to identify areas in jurisdictional EHDI systems that may require additional modification. This is anticipated to be helpful in providing technical support to funded jurisdictions as well as for assessing the impact of federal initiatives related to hearing loss in infants and children.

Fourth, the requested data will aid in efforts to determine the prevalence of differing degrees of hearing loss (e.g., mild, severe, profound, etc.) among infants and children.

Information provided by this updated survey also has the potential to be used for other purposes. These include

quality improvement activities by jurisdictional EHDI programs (e.g., identifying areas within the EHDI processes that could benefit from further development) and providing requested data for Healthy People 2020, Objective ENT-VSL-1 on newborn hearing screening, evaluation, and intervention. In addition, the aggregate-level data will continue to be made available online to other state and federal agencies, organizations, and the general public.

The total burden hours is 238.

#### Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
EHDI Program State Program Coordinators Contacted	Survey Directions	59	1	10/60	10
EHDI Program State Program Coordinators who return the survey	Survey	57	1	240/60	228
Totals					238

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Leroy A. Richardson  
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 Office of Scientific Integrity  
 Office of the Associate Director for Science

Office of the Director  
Centers for Disease Control and Prevention  
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